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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

CV 12-02409 HRL

DARYL DE KECZER, individually and on behalf of all others similarly situated,

Plaintiff,

v.

TETLEY USA, INC.,

Defendant

Case No.

CLASS ACTION AND REPRESENTATIVE ACTION

COMPLAINT FOR DAMAGES, EQUITABLE AND INJUNCTIVE RELIEF

JURY TRIAL DEMANDED

Plaintiff, through his undersigned attorneys, brings this lawsuit against Defendant as to his own acts upon personal knowledge, and as to all other matters upon information and belief. In order to remedy the harm arising from Defendant's illegal conduct, which has resulted in unjust profits, Plaintiff brings this action on behalf of a class of California consumers who purchased Defendant's: (1) Classic Blend Black Tea, (2) British Blend Black Tea, (3) Pure Green Tea, (4) Iced Tea Blend Tea, and/or (5) Iced Tea Mix Tea ("Misbranded Food Products") within the last four years.

INTRODUCTION

1. Every day, millions of Americans purchase and consume packaged foods. Identical federal and California laws require truthful, accurate information on the labels of packaged foods. This case is about a company that flouts those laws, before and after companies with identical products with similar claims on their labels received warning letters from the FDA. The law is clear: misbranded food cannot legally be manufactured, held, advertised, distributed or sold. Misbranded food is worthless as a matter of law, and purchasers of misbranded food are entitled to a refund of their purchase price.

2. Defendant Tetley USA, Inc. (hereinafter "Tetley" or "Defendant") is a tea company based in New Jersey. Tetley is a wholly owned subsidiary of Tata Global Beverages, Ltd. a conglomerate headquartered in Kolkata, West Bengal India. Tetley is the largest tea company by volume in the United Kingdom and Canada and the second largest in the United States.

3. Tata Global Beverages, Ltd., Tetley's parent, recognizes that health claims drive sales. It actively encourages its subsidiary Tetley to promote the alleged health benefits to consumers from using Tetley tea products. For example, in its 2009-2010 annual report, Tata Global stated:

> The global beverage market offers significant opportunities for growth. Markets for specialty tea, green tea, ready-to-drink beverages and fruit juices are growing far quicker than traditional black tea. These new areas give us opportunities to focus on the growing health and wellness segment with convenient products, delivered to consumers in a sustainable way.

http://www.tataglobalbeverages.com/Lists/Document%20Manager/Attachments/21/tata-tea-annual-report-2010.pdf.

4. On its own website, Tetley goes even further in promoting the health benefits of its tea products, specifically focusing on claimed nutrients in its tea known as antioxidants:

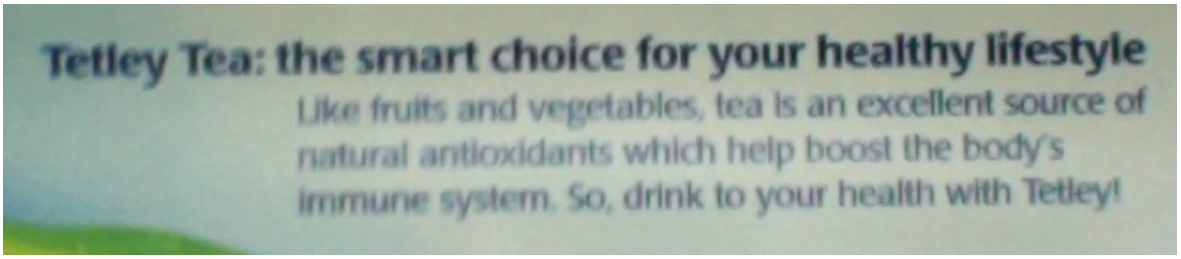
> Tea, like fruits and vegetables, is an excellent source of antioxidants. Antioxidants, in a nutshell (or a teacup, as the case may be), are compounds that prevent or delay oxidative damage to the body, cells and tissue brought on by free radicals. There are two basic categories of antioxidants: those that are produced naturally by your body, and those that are supplied by your diet—and

> that's where Tetley can help.
>
> All black, green, white and red (rooibos) teas contain powerful and natural antioxidants called flavonoids. Flavonoid antioxidant levels are generally higher in green and white teas, as they are taken from the early leaves and buds from the tea plant, *Camellia sinensis*, and undergo less processing than other teas.
>
> A growing body of evidence suggests that the antioxidants that occur naturally in tea can help your body in various ways, such as:
>
> - Neutralize free radicals that can cause cell damage linked to certain cancers
> - Inhibit the oxidation of LDL (bad cholesterol), helping you fight heart disease
> - Boost your immune system4 and help reduce infections by as much as 87%
> - A recent 2007 study conducted in the UK revealed that those who drank two or more cups of green tea a day had a 65% lower risk of developing squamous cell carcinoma
> - Studies have shown that black tea may protect lungs from damage caused by exposure to cigarette smoke and may also reduce the risk of stroke
> - A study published in the February 2009 *Journal of Nutrition* suggests that green tea may reduce the risk of breast cancer if plentiful amounts of the beverage are consumed over many years
> - Provide a boost to exercise-induced weight loss
>
> http://www.tetleyusa.com/AboutTea_TeaAndHealth.php

5. In doing so, Tetley utilizes improper antioxidant, nutrient content, and health claims that have been expressly condemned by the FDA in numerous enforcement actions and warning letters.

6. For example, Tetley makes unlawful antioxidant, nutrient content and health claims directly on packages of its tea products. The package back panel of Tetley Iced Tea Blend, shown below, bears the statement: "*Tetley Tea: the smart choice for your healthy lifestyle: Like fruits and vegetables, tea is an excellent source of natural antioxidants which help boost the body's immune system. So, drink to your health with Tetley*." It also states on the front panel that the Tetley tea is a "natural source of antioxidants."

Such claims have been repeatedly targeted by the FDA as unlawful for tea and other food products.



7. These same unlawful antioxidant, nutrient content and health claims are on each label of the Misbranded Food Products.

8. If a manufacturer is going to make a claim on a food label, the label must meet certain legal requirements that help consumers make informed choices and ensure that they are not misled. As described more fully below, Defendant has made, and continues to make, false and deceptive claims in violation of federal and California laws that govern the types of representations that can be made on food labels. These laws recognize that reasonable consumers are likely to choose products claiming to have a health or nutritional benefit over otherwise similar food products that do not claim such benefits.

9. Identical federal and California laws regulate the content of labels on packaged food. The requirements of the federal Food Drug & Cosmetic Act, 21 U.S.C. § 301, *et seq*. ("FDCA") were adopted by the California legislature in the Sherman Food Drug & Cosmetic Law, California Health & Safety Code § 109875, *et seq*. (the "Sherman Law"). Under FDCA section 403(a), food is "misbranded" if "its labeling is false or misleading in any particular," or if it does not contain certain information on its label or in its labeling. 21 U.S.C. § 343(a).

10. Under the FDCA, the term "false" has its usual meaning of "untruthful," while the term "misleading" is a term of art. Misbranding reaches not only false claims, but also those claims that might be technically true, but still misleading. If any one representation in the labeling is misleading, then the entire food is misbranded, and no other statement in the labeling can cure a misleading statement. "Misleading" is judged in reference to "the ignorant, the unthinking and the credulous who, when making a purchase, do not stop to analyze." *United States v. El-O-Pathic Pharmacy*, 192 F.2d 62, 75 (9th Cir. 1951). Under the FDCA, it is not necessary to prove that anyone was actually misled.

11. On August 23, 2010, the United States Food and Drug Administration ("FDA") sent a warning letter to Unilever, the parent company of Lipton Tea, one of Tetley's biggest competitors, informing Unilever of Lipton Tea's failure to comply with FDCA and its regulations (the "FDA Warning Letter," attached hereto as Exhibit 1 and made a part hereof by reference) for remarkably similar nutrient content claims to those Tetley is presently making on its product labels. The FDA Warning Letter to Unilever stated, in pertinent part:

> **Unauthorized Nutrient Content Claims**
>
> Under section 403(r)(1)(A) of the Act [21 U.S.C. 343(r)(1)(A)], a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.
>
> Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the

> term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.
>
> Your webpage entitled "Tea and Health" and subtitled "Tea Antioxidants" includes the statement, "LIPTON Tea is made from tea leaves rich in naturally protective antioxidants." The term "rich in" is defined in 21 CFR 101.54(b) and may be used to characterize the level of antioxidant nutrients (21 CFR 101.54(g)(3)). However, this claim does not comply with 21 CFR 101.54(g)(4) because it does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients. Thus, this claim misbrands your product under section 403(r)(2)(A)(i) of the Act.
>
> This webpage also states: "[t]ea is a naturally rich source of antioxidants." The term "rich source" characterizes the level of antioxidant nutrients in the product and, therefore, this claim is a nutrient content claim (see section 403(r)(1) of the Act and 21 CFR 101.13(b)). Even if we determined that the term "rich source" could be considered a synonym for a term defined by regulation (e.g., "high" or "good source"), nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). The claim "tea is a naturally rich source of antioxidants" does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients, as required by 21 CFR 101.54(g)(4). Thus, this claim misbrands your product under section 403(r)(2)(A)(i) of the Act.
>
> The product label back panel includes the statement "packed with protective FLAVONOID ANTIOXIDANTS." The term "packed with" characterizes the level of flavonoid antioxidants in the product; therefore, this claim is a nutrient content claim (see section 403(r)(1) of the Act and 21 CFR 101.13(b)). Even if we determined that the term "packed with" could be considered a synonym for a term defined by regulation, nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). The claim "packed with FLAVONOID ANTIOXIDANTS" does not comply with 21 CFR 101.54(g)1) because no RDI has been established for flavonoids. Thus, this unauthorized nutrient content claim causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.
>
> The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm224509.htm.

12. As shown above, the label of Tetley's Misbranded Food Products represents that the tea products are "an excellent source of natural antioxidants" and also "[a] natural source of

antioxidants." The label also touts claimed health benefits from drinking these tea products. As determined by the FDA in the Unilever/Lipton and other warning letters, such antioxidant, nutrient content and health claims are in violation of 21 U.S.C. § 352(f)(1), and therefore the products are misbranded.

13. Defendant has made, and continues to make, food label claims that are prohibited by federal and California law. Under federal and California law, Defendant's Misbranded Food Products cannot legally be manufactured, advertised, distributed, held or sold. Defendant's false and misleading labeling practices stem from their global marketing strategy. The violations and misrepresentations are similar across Defendant's product labels and product lines.

PARTIES

14. Plaintiff Daryl de Keczer is a resident of San Jose, California who purchased Tetley's Misbranded Food Products in California during the four (4) years prior to the filing of this Complaint (the "Class Period").

15. Defendant Tetley USA, Inc. is a Delaware corporation with its principle place of business in New Jersey. Tetley USA, Inc. is authorized to do business in California.

16. Tetley is a leading producer of retail tea products. Tetley sells its Misbranded Food Products to consumers throughout California via grocery stores, other retail stores and through its website.

JURISDICTION AND VENUE

17. This Court has original jurisdiction over this action under 28 U.S.C. § 1332(d) because this is a class action in which: (1) there are over 100 members in the proposed class; (2) members of the proposed class have a different citizenship from Defendant; and (3) the claims of the proposed class members exceed $5,000,000 in the aggregate.

18. The Court has jurisdiction over the federal claim alleged herein pursuant to 28 U.S.C. § 1331, because it arises under the laws of the United States.

19. The Court has jurisdiction over the California claims alleged herein pursuant to 28 U.S.C. § 1367, because they form part of the same case or controversy under Article III of the United States Constitution.

20. Alternatively, the Court has jurisdiction over all claims alleged herein pursuant to 28 U.S.C. § 1332, because the matter in controversy exceeds the sum or value of $75,000, and is between citizens of different states.

21. The Court has personal jurisdiction over Defendant because a substantial portion of the wrongdoing alleged in this Complaint occurred in California, Defendant is authorized to do business in California, has sufficient minimum contacts with California, and otherwise intentionally avails itself of the markets in California through the promotion, marketing and sale of merchandise, sufficient to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

22. Because a substantial part of the events or omissions giving rise to these claims occurred in this District and because the Court has personal jurisdiction over Defendant, venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (b).

FACTUAL ALLEGATIONS

A. Identical California And Federal Laws Regulate Food Labeling

23. Food manufacturers are required to comply with federal and state laws and regulations that govern the labeling of food products. First and foremost among these is the FDCA and its labeling regulations, including those set forth in 21 C.F.R. § 101.

24. Pursuant to the Sherman Law, California has expressly adopted the federal labeling requirements as its own and indicated that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food regulations of this state." California Health & Safety Code § 110100.

25. In addition to its blanket adoption of federal labeling requirements, California has also enacted a number of laws and regulations that adopt and incorporate specific enumerated federal food laws and regulations. For example, food products are misbranded

under California Health & Safety Code § 110660 if their labeling is false and misleading in one or more particulars; are misbranded under California Health & Safety Code § 110665 if their labeling fails to conform to the requirements for nutrient labeling set forth in 21 U.S.C. § 343(q) and regulations adopted thereto; are misbranded under California Health & Safety Code § 110670 if their labeling fails to conform with the requirements for nutrient content and health claims set forth in 21 U.S.C. § 343(r) and regulations adopted thereto; are misbranded under California Health & Safety Code § 110705 if words, statements and other information required by the Sherman Law to appear on their labeling are either missing or not sufficiently conspicuous; are misbranded under California Health & Safety Code § 110735 if they are represented as having special dietary uses but fail to bear labeling that adequately informs consumers of their value for that use; and are misbranded under California Health & Safety Code § 110740 if they contain artificial flavoring, artificial coloring and chemical preservatives but fail to adequately disclose that fact on their labeling.

B. FDA Enforcement History

26. In recent years the FDA has become increasingly concerned that food manufacturers were disregarding food labeling regulations. To address this concern, the FDA elected to take steps to inform the food industry of its concerns and to place the industry on notice that food labeling compliance was an area of enforcement priority.

27. In October 2009, the FDA issued a *Guidance For Industry: Letter Regarding Point Of Purchase Food Labeling* to address its concerns about front of package labels ("2009 FOP Guidance"). The 2009 FOP Guidance advised the food industry:

> FDA's research has found that with FOP labeling, people are less likely to check the Nutrition Facts label on the information panel of foods (usually, the back or side of the package). It is thus essential that both the criteria and symbols used in front-of-package and shelf-labeling systems be nutritionally sound, well-designed to help consumers make informed and healthy food choices, and not be false or misleading. The agency is currently analyzing FOP labels that appear to be misleading. The agency is also looking for symbols that either expressly or by implication are nutrient content claims. We are assessing the criteria established by food manufacturers for such symbols and comparing them to our regulatory criteria.

> It is important to note that nutrition-related FOP and shelf labeling, while currently voluntary, is subject to the provisions of the Federal Food, Drug, and Cosmetic Act that prohibit false or misleading claims and restrict nutrient content claims to those defined in FDA regulations. Therefore, FOP and shelf labeling that is used in a manner that is false or misleading misbrands the products it accompanies. Similarly, a food that bears FOP or shelf labeling with a nutrient content claim that does not comply with the regulatory criteria for the claim as defined in Title 21 Code of Federal Regulations (CFR) 101.13 and Subpart D of Part 101 is misbranded. We will consider enforcement actions against clear violations of these established labeling requirements. . .
>
> … Accurate food labeling information can assist consumers in making healthy nutritional choices. FDA intends to monitor and evaluate the various FOP labeling systems and their effect on consumers' food choices and perceptions. FDA recommends that manufacturers and distributors of food products that include FOP labeling ensure that the label statements are consistent with FDA laws and regulations. FDA will proceed with enforcement action against products that bear FOP labeling that are explicit or implied nutrient content claims and that are not consistent with current nutrient content claim requirements. FDA will also proceed with enforcement action where such FOP labeling or labeling systems are used in a manner that is false or misleading.

28. The 2009 FOP Guidance recommended that "manufacturers and distributors of food products that include FOP labeling ensure that the label statements are consistent with FDA law and regulations" and specifically advised the food industry that it would "proceed with enforcement action where such FOP labeling or labeling systems are used in a manner that is false or misleading."

29. Despite the issuance of the 2009 FOP Guidance, Defendant did not remove the unlawful and misleading food labeling claims from their Misbranded Food Products.

30. On March 3, 2010, the FDA issued an "Open Letter to Industry from [FDA Commissioner] Dr. Hamburg" (hereinafter, "Open Letter"). The Open Letter reiterated the FDA's concern regarding false and misleading labeling by food manufacturers. In pertinent part the letter stated:

> In the early 1990s, the Food and Drug Administration (FDA) and the food industry worked together to create a uniform national system of nutrition labeling, which includes the now-iconic Nutrition Facts panel on most food packages. Our citizens appreciate that effort, and many use this nutrition information to make food choices. Today, ready access to reliable information about the calorie and nutrient content of food is even more important, given the

prevalence of obesity and diet-related diseases in the United States. This need is highlighted by the announcement recently by the First Lady of a coordinated national campaign to reduce the incidence of obesity among our citizens, particularly our children.

With that in mind, I have made improving the scientific accuracy and usefulness of food labeling one of my priorities as Commissioner of Food and Drugs. The latest focus in this area, of course, is on information provided on the principal display panel of food packages and commonly referred to as "front-of-pack" labeling. The use of front-of-pack nutrition symbols and other claims has grown tremendously in recent years, and it is clear to me as a working mother that such information can be helpful to busy shoppers who are often pressed for time in making their food selections. …

As we move forward in those areas, I must note, however, that there is one area in which more progress is needed. As you will recall, we recently expressed concern, in a "Dear Industry" letter, about the number and variety of label claims that may not help consumers distinguish healthy food choices from less healthy ones and, indeed, may be false or misleading.

At that time, we urged food manufacturers to examine their product labels in the context of the provisions of the Federal Food, Drug, and Cosmetic Act that prohibit false or misleading claims and restrict nutrient content claims to those defined in FDA regulations. As a result, some manufacturers have revised their labels to bring them into line with the goals of the Nutrition Labeling and Education Act of 1990. Unfortunately, however, we continue to see products marketed with labeling that violates established labeling standards.

To address these concerns, FDA is notifying a number of manufacturers that their labels are in violation of the law and subject to legal proceedings to remove misbranded products from the marketplace. While the warning letters that convey our regulatory intentions do not attempt to cover all products with violative labels, they do cover a range of concerns about how false or misleading labels can undermine the intention of Congress to provide consumers with labeling information that enables consumers to make informed and healthy food choices

. . . .

These examples and others that are cited in our warning letters are not indicative of the labeling practices of the food industry as a whole. In my conversations with industry leaders, I sense a strong desire within the industry for a level playing field and a commitment to producing safe, healthy products. That reinforces my belief that FDA should provide as clear and consistent guidance as possible about food labeling claims and nutrition information in general, and specifically about how the growing use of front-of-pack calorie and nutrient information can best help consumers construct healthy diets.

> I will close with the hope that these warning letters will give food manufacturers further clarification about what is expected of them as they review their current labeling. I am confident that our past cooperative efforts on nutrition information and claims in food labeling will continue as we jointly develop a practical, science-based front-of-pack regime that we can all use to help consumers choose healthier foods and healthier diets.

31. Notwithstanding the Open Letter, Defendant continued to utilize unlawful food labeling claims despite the express guidance of the FDA in the Open Letter.

32. In addition to its guidance to industry, the FDA has sent warning letters to industry, including many of Defendant's peer food manufacturers for the same types of unlawful nutrient content claims described above.

33. In these letters the FDA indicated that, as a result of the same type of claims utilized by Defendant, products were in "violation of the Federal Food, Drug, and Cosmetic Act … and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR § 101)" and "misbranded within the meaning of section 403(r)(1)(A) because the product label bears a nutrient content claim but does not meet the requirements to make the claim."

34. The warning letters were hardly isolated as the FDA has issued other warning letters to other companies for the same type of food labeling claims at issue in this case.

35. The FDA stated that the agency not only expected companies that received warning letters to correct their labeling practices but also anticipated that other firms would examine their food labels to ensure that they are in full compliance with food labeling requirements and make changes where necessary. Defendant did not change the labels on its Misbranded Food Products in response to these warning letters.

36. Defendant also continued to ignore the 2009 FOP Guidance which detailed the FDA's guidance on how to make food labeling claims. Defendant ignored this guidance as well and continued to utilize unlawful claims on the labels of their Misbranded Food Products. As such, the Defendant's Misbranded Food Products continue to run afoul of 2009 FOP Guidance as well as federal and California law.

37. Despite the FDA's numerous warnings to industry, Defendant has continued to sell products bearing unlawful food labeling claims without meeting the requirements to make them.

38. Plaintiff did not know, and had no reason to know, that the Defendant's Misbranded Food Products were misbranded and bore food labeling claims despite failing to meet the requirements to make those food labeling claims.

C. Defendant's Food Products Are Misbranded

39. Pursuant to Section 403 of the FDCA, a claim that characterizes the level of a nutrient in a food is a "nutrient content claim" that must be made in accordance with the regulations that authorize the use of such claims. 21 U.S.C. § 343(r)(1)(A). California expressly adopted the requirements of 21 U.S.C. § 343(r) in § 110670 of the Sherman Law.

40. Nutrient content claims are claims about specific nutrients contained in a product. They are typically made on the front of packaging in a font large enough to be read by the average consumer. Because these claims are relied upon by consumers when making purchasing decisions, the regulations govern what claims can be made in order to prevent misleading claims.

41. Section 403(r)(1)(A) of the FDCA governs the use of expressed and implied nutrient content claims on labels of food products that are intended for sale for human consumption. *See* 21 C.F.R. § 101.13.

42. 21 C.F.R. § 101.13 provides the general requirements for nutrient content claims, which California has expressly adopted. *See* California Health & Safety Code § 110100. 21 C.F.R. § 101.13 requires that manufacturers include certain disclosures when a nutrient claim is made and, at the same time, the product contains certain levels of unhealthy ingredients, such as fat and sodium. It also sets forth the manner in which that disclosure must be made, as follows:

> (4)(i) The disclosure statement "See nutrition information for ___ content" shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, and in a size no less than that required by §101.105(i) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclosure statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch, unless the package

> complies with §101.2(c)(2), in which case the disclosure statement may be in type of not less than one thirty-second of an inch.
>
> (ii) The disclosure statement shall be immediately adjacent to the nutrient content claim and may have no intervening material other than, if applicable, other information in the statement of identity or any other information that is required to be presented with the claim under this section (e.g., see paragraph (j)(2) of this section) or under a regulation in subpart D of this part (e.g., see §§101.54 and 101.62). If the nutrient content claim appears on more than one panel of the label, the disclosure statement shall be adjacent to the claim on each panel except for the panel that bears the nutrition information where it may be omitted.

43. An "expressed nutrient content claim" is defined as any direct statement about the level (or range) of a nutrient in the food (*e.g.*, "low sodium" or "contains 100 calories"). *See* 21 C.F.R. § 101.13(b)(1).

44. An "implied nutrient content claim" is defined as any claim that: (i) describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (*e.g.*, "high in oat bran"); or (ii) suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (*e.g.*, "healthy, contains 3 grams (g) of fat"). 21 C.F.R. § 101.13(b)(2)(i-ii).

1. <u>Defendant Makes Unlawful Antioxidant Claims</u>

45. Federal and California regulations regulate antioxidant claims as a particular type of nutrient content claim. Specifically, 21 C.F.R. § 101.54(g) contains special requirements for nutrient claims that use the term "antioxidant":

(1) the name of the antioxidant must be disclosed;

(2) there must be an established Recommended Daily Intake ("RDI") for that antioxidant, and if not, no "antioxidant" claim can be made about it;

(3) the label claim must include the specific name of the nutrient that is an antioxidant and cannot simply say "antioxidants" (*e.g.*, "high in antioxidant vitamins C and E"),[1] *see* 21 C.F.R. § 101.54(g)(4);

[1] Alternatively, when used as part of a nutrient content claim, the term "antioxidant" or "antioxidants" (such as "high in antioxidants") may be linked by a symbol (such as an asterisk) that refers to the same symbol that appears elsewhere on the same panel of a product label followed by the name or names of the nutrients with the recognized

(4) the nutrient that is the subject of the antioxidant claim must also have recognized antioxidant activity, *i.e.*, there must be scientific evidence that after it is eaten and absorbed from the gastrointestinal tract, the substance participates in physiological, biochemical or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions, *see* 21 C.F.R. § 101.54(g)(2);

(5) the antioxidant nutrient must meet the requirements for nutrient content claims in 21 C.F.R. § 101.54(b), (c), or (e) for "High" claims, "Good Source" claims, and "More" claims, respectively. For example, to use a "High" claim, the food would have to contain 20% or more of the Daily Reference Value ("DRV") or RDI per serving. For a "Good Source" claim, the food would have to contain between 10-19% of the DRV or RDI per serving, *see* 21 C.F.R. § 101.54(g)(3); and

(6) the antioxidant nutrient claim must also comply with general nutrient content claim requirements such as those contained in 21 C.F.R. § 101.13(h) that prescribe the circumstances in which a nutrient content claim can be made on the label of products high in fat, saturated fat, cholesterol or sodium.

46. The antioxidant labeling for Tetley's Misbranded Food Products and the claims on Tetley's website promoting these products violate California law: (1) because the names of the antioxidants are not disclosed on the product labels; (2) because there are no RDIs for the antioxidants being touted, including flavonoids and polyphenols; (3) because the claimed antioxidant nutrients fail to meet the requirements for nutrient content claims in 21 C.F.R. § 101.54(b), (c), or (e) for "High" claims, "Good Source" claims, and "More" claims, respectively; and (4) because Defendant lacks adequate scientific evidence that the claimed antioxidant nutrients participate in physiological, biochemical, or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions after they are eaten and absorbed from the gastrointestinal tract.

antioxidant activity. If this is done, the list of nutrients must appear in letters of a type size height no smaller than the larger of one half of the type size of the largest nutrient content claim or 1/16 inch.

47. For example, as discussed in paragraph 6 above, the package label of Tetley's Iced Tea Blend product bears the statements "an excellent source of natural antioxidants" and "[a] natural source of antioxidants." The label further touts the health benefits of the product and compares it to fruits and vegetables. As discussed in paragraph 4 above, Tetley also touts on its website alleged health benefits to be derived from using its tea products. These same violations were condemned in the FDA Warning Letter to Unilever/Lipton discussed above and attached as Exhibit 1. These same violations were condemned in numerous other warning letters to other tea companies including the April 11, 2011 warning letter to Diaspora Tea & Herb Co., LLC (attached as Exhibit 2) which states in pertinent part:

> Additionally, your website bears nutrient content claims using the term "antioxidant." Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a Recommended Daily Intake (RDI) must have been established for each of the nutrients that are the subject of the claim, 21 CFR 101.54(g)(1), and these nutrients must have recognized antioxidant activity, 21 CFR 101.54(g)(2). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e), 21 CFR 101.54(g)(3). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity, 21 CFR 101.54(g)(4). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act. The following are examples of nutrient content claims on your website that use the term "antioxidant" but do not include the names of the nutrients that are the subject of the claim as required under 21 CFR 101.54(g)(4): "Yerba Maté is…rich in… antioxidants." ; … "Caffeine-free Green Rooibos…contain[s] high concentrations of antioxidants….
>
> Additionally, the following are examples of nutrient content claims on your website that use the term "antioxidant," but where the nutrients that are the subject of the claim do not have an established RDI as required under 21 CFR 101.54(g)(1): … "White Tea… contain[s] high concentrations of… antioxidant polyphenols (tea catechins)…." ; … "Antioxidant rich…222mg polyphenols per serving!"; … "Antioxidant rich…109mg polyphenols per serving!"
>
> The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products

> marketed by your firm comply with the Act and its implementing regulations. We urge you to review your website, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products, 21 U.S.C. §§ 332 and 334

48. For these reasons, Defendant's antioxidant claims at issue in this Complaint are misleading and in violation of 21 C.F.R. § 101.54 and California law, and the products at issue are misbranded as a matter of law. Misbranded products cannot be legally manufactured, advertised, distributed, held or sold and are legally worthless. Plaintiff and members of the Class who purchased these products paid an unwarranted premium for these products.

49. In addition to the FDA Warning Letters to Unilever and Diaspora Tea & Herb Co., LLC discussed above (Exhibits 1 and 2), the FDA has issued numerous warning letters addressing similar unlawful antioxidant nutrient content claims. *See, e.g.*, Exhibit 3 (FDA warning letter dated February 22, 2010 to Redco Foods, Inc. regarding its misbranded Salada Naturally Decaffeinated Green Tea product because "there are no RDIs for (the antioxidants) grapeskins, rooibos (red tea) and anthocyanins"); Exhibit 4 (FDA warning letter dated February 22, 2010 to Fleminger Inc. regarding its misbranded TeaForHealth products because the admonition "[d]rink high antioxidant green tea" . . . "does not include the nutrients that are the subject of the claim or use a symbol to link the term antioxidant to those nutrients"). These warning letters were hardly isolated. Defendant is aware of these FDA warning letters.

50. Additional evidence of Tetley's knowledge that its antioxidant health claims are improper and misleading is provided by the November 25, 2009 Adjudication of the British Advertising Standards Authority ("ASA"). There, the ASA found that Tetley's print and TV advertisements stating that Tetley products were: "rich in antioxidants that can keep your heart healthy" were misleading. In so holding, ASA stated:

> Because the evidence we had seen was not directly relevant to the implied claim that green tea, or the antioxidants in it, had general health benefits, we considered it was not sufficient substantiation for that claim. We concluded that the ad was misleading.
>
> On this point, the ad breached CAP (Broadcast) TV Advertising Standards Code

> rules 5.1.1 (Misleading advertising), 5.2.1 (Evidence), 5.2.2 (Implications), 8.3.1(a) (Accuracy in food advertising)
>
> The ad must not be broadcast again in its current form. We told Tetley not to imply that a product had greater health benefits than it did if they did not hold substantiation for the implied claims….

Adjudication of the ASA Council, Tetley GB Ltd., November 25, 2009.

http://www.asa.org.uk/ASA-action/Adjudications/2009/11/Tetley-GB-Ltd/TF_ADJ_47670.aspx

51. The types of misrepresentations made above would be considered by a reasonable consumer when deciding to purchase the products. Not only do Tetley's antioxidant, nutrient content and health claims regarding the benefits of "flavonoids" violate FDA rules and regulations, they directly contradict current scientific research, which has concluded: "[T]he evidence today does not support a direct relationship between tea consumption and a physiological AOX [antioxidant] benefit." This conclusion was reported by Dr. Jane Rycroft, Director of Lipton Tea Institute of Tea, in an article published in January, 2011, in which Dr. Rycroft states:

> Only a few scientific publications report an effect of tea on free radical damage in humans using validated biomarkers in well designed human studies. Unfortunately, the results of these studies are at variance and the majority of the studies do not report significant effects . . .
>
> Therefore, despite more than 50 studies convincingly showing that flavonoids possess potent antioxidant activity *in vitro*, the ability of flavonoids to act as an antioxidant *in vivo* [in humans], has not been demonstrated.
>
> Based on the current scientific consensus that the evidence today does not support a direct relationship between tea consumption and a physiological AOX benefit…
>
> No evidence has been provided to establish that having antioxidant activity/content and/or antioxidant properties is a beneficial physiological effect.

Rycroft, Jane, "The Antioxidant Hypothesis Needs to be Updated," Vol. 1, *Tea Quarterly Tea Science Overview*, Lipton Tea Institute of Tea Research (Jan. 2011), pp. 2-3.

52. This scientific evidence and consensus conclusively establishes the improper nature of the Defendant's antioxidant claims as they cannot possibly satisfy the legal and regulatory requirement that the nutrient that is the subject of the antioxidant claim must also

have recognized antioxidant activity, *i.e.*, there must be scientific evidence that after it is eaten and absorbed from the gastrointestinal tract, the substance participates in physiological, biochemical or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions, *see* 21 C.F.R. § 101.54(g)(2).

2. Defendant Makes Unlawful Nutritional Content Claims

53. FDA regulations authorize use of a limited number of defined nutrient content claims. In addition to authorizing the use of only a limited set of defined nutrient content terms on food labels, FDA's regulations authorize the use of only certain synonyms for these defined terms. If a nutrient content claim or its synonym is not included in the food labeling regulations it cannot be used on a label. Only those claims, or their synonyms, that are specifically defined in the regulations may be used. All other claims are prohibited. 21 CFR § 101.13(b).

54. Only approved nutrient content claims will be permitted on the food label, and all other nutrient content claims will misbrand a food. It should thus be clear which type of claims are prohibited and which are permitted. Manufacturers are on notice that the use of an unapproved nutrient content claim is prohibited conduct. 58 FR 2302. In addition, 21 U.S.C. § 343(r)(2) prohibits using unauthorized undefined terms and declares foods that do so to be misbranded.

55. In order to appeal to consumer preferences, Defendant has repeatedly made unlawful nutrient content claims about antioxidants and other nutrients that fail to utilize one of the limited defined terms. These nutrient content claims are unlawful because they failed to comply with the nutrient content claim provisions in violation of 21 C.F.R. §§ 101.13 and 101.54, which have been incorporated in California's Sherman Law. To the extent that the terms used to describe antioxidants without a recognized daily value or RDI (such as "natural source") are deemed to be a synonym for a defined term like "contain" the claim would still be unlawful because, as these nutrients do not have established daily values, they cannot serve as the basis for a term that has a minimum daily value threshold.

56. Similarly, the regulations specify absolute and comparative levels at which foods qualify to make these claims for particular nutrients (*e.g.*, low fat. . . more vitamin C.) and list

synonyms that may be used in lieu of the defined terms. Certain implied nutrient content claims (*e.g.*, healthy) also are defined. The daily values ("DVs") for nutrients that the FDA has established for nutrition labeling purposes have application for nutrient content claims, as well. Claims are defined under current regulations for use with nutrients having established DVs; moreover, relative claims are defined in terms of a difference in the percent DV of a nutrient provided by one food as compared to another. *See. e.g.* 21 C.F.R. §§ 101.13 and 101.54.

57. Defendant has repeatedly made unlawful nutrient content claims about antioxidants and other nutrients that fail to utilize one of the limited defined terms appropriately. These nutrient content claims are unlawful because they fail to comply with the nutrient content claim provisions in violation of 21 C.F.R. §§ 101.13 and 101.54, which have been incorporated in California's Sherman Law.

58. For example, claims that Tetley's teas are "an excellent source of antioxidants" are unlawful Defendant's teas do not meet the minimum nutrient level threshold to make such a claim which is 20 percent or more of the RDI or the DRV of a nutrient per reference amount customarily consumed.

59. The nutrient content claims regulations discussed above are intended to ensure that consumers are not misled as to the actual or relative levels of nutrients in food products.

60. Defendant has violated these referenced regulations. Therefore, Defendant's Misbranded Food Products are misbranded as a matter of federal and California law and cannot be sold or held because they are legally worthless. Defendant has also violated 21 C.F.R. § 101.54(g)(1), which prohibits food manufacturers from making claims regarding the nutritional value of their products when the products fail to disclose that no RDI has been established for the touted nutrients.

61. For example, Tetley Misbranded Food Products claim to be "an excellent source of antioxidants" or "a natural source of antioxidants" but they fail to disclose that no RDI has been established for any antioxidant nutrient in its tea products, including flavonoids. Thus, these products violate 21 C.F.R. § 101.54(g)(1).

62. Claims that Tetley products contain or are made with an ingredient such as tea that is represented to contain a particular nutrient, or is prepared in a way that affects the content of a particular nutrient in the food, can only be made if it at least a ‘‘good source’’ of the nutrient that is associated with the ingredient or type of preparation. Thus, Tetley's statements that tea is a "natural source" of antioxidants trigger a "good source" requirement (10 percent or more of the RDI or the DRV per reference amount customarily consumed) which tea cannot demonstrate. 21 C.F.R. § 101.65(c)(3).

63. The type of misrepresentations made above would be considered by a reasonable consumer when deciding to purchase Defendant's Misbranded Food Products. The failure to comply with the labeling requirements of 21 C.F.R. § 101.54 renders Defendant's products misbranded as a matter of federal and California law.

64. In addition, 21 C.F.R. § 101.65, which has been adopted by California, sets certain minimum nutritional requirements for making an implied nutrient content claim that a product is healthy. For example, for unspecified foods, the food must contain at least 10 percent of the RDI of one or more specified nutrients. Defendant has misrepresented the healthiness of their products while failing to meet the regulatory requirements for making such claims.

3. Defendant Makes Unlawful Health Claims

65. A health claim is a statement expressly or implicitly linking the consumption of a food substance (*e.g.*, ingredient, nutrient, or complete food) to risk of a disease (*e.g.*, cardiovascular disease) or a health-related condition (*e.g.*, hypertension). *See* 21 C.F.R. § 101.14(a)(1), (a)(2), and (a)(5). Only health claims made in accordance with FDCA requirements, or authorized by FDA as qualified health claims, may be included in food labeling. Other express or implied statements that constitute health claims, but that do not meet statutory requirements, are prohibited in labeling foods.

66. 21 C.F.R. § 101.14, which has been expressly adopted by California, provides when and how a manufacturer may make a health claim about its product. A "Health Claim" means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (*e.g.*, a brand

name including a term such as "heart"), symbols (*e.g.*, a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition (*see* 21 CFR § 101.14(a)(1)).

67. Further, health claims are limited to claims about disease risk reduction, and cannot be claims about the diagnosis, cure, mitigation, or treatment of disease. An example of an authorized health claim is: "Three grams of soluble fiber from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the risk of heart disease. This cereal has 2 grams per serving."

68. A claim that a substance may be used in the diagnosis, cure, mitigation, treatment, or prevention of a disease is a drug claim and may not be made for a food. 21 U.S.C. § 321(g)(1)(D).

69. The use of the term "healthy" is not a health claim but rather an implied nutrient content claim about general nutrition that is defined by FDA regulation. In general, the term may be used in labeling an individual food product that:

> Qualifies as both low fat and low saturated fat;
>
> Contains 480 mg or less of sodium per reference amount and per labeled serving, and per 50 g (as prepared for typically rehydrated foods) if the food has a reference amount of 30 g or 2 tbsps or less;
>
> Does not exceed the disclosure level for cholesterol (*e.g.*, for most individual food products, 60 mg or less per reference amount and per labeled serving size); *and*
>
> Except for raw fruits and vegetables, certain frozen or canned fruits and vegetables, and enriched cereal-grain products that conform to a standard of identity, provides at least 10% of the daily value (DV) of vitamin A, vitamin C, calcium, iron, protein, *or* fiber per reference amount. Where eligibility is based on a nutrient that has been added to the food, such fortification must comply with FDA's fortification policy.

21 C.F.R. § 101.65(d)(2). The FDA's definition applies separate criteria to use of healthy on

raw, single ingredient seafood or game meat products. 21 C.F.R. § 101.65(d)(2)(ii). FDA's regulation on healthy also encompasses other, derivative uses of health (*e.g.*, healthful, healthier) in food labeling. 21 C.F.R. § 101.65(d).

70. Tetley has violated the provisions of 21 C.F.R. § 101.14, 21 C.F.R. § 101.65, 21 U.S.C. § 321(g)(1)(D) and 21 U.S.C. § 352(f)(1) on a number of its products and on its websites. For example, the claim on the package back panel that "like fruit and vegetables tea is an excellent source of antioxidants which help boost the body's immune system" is in violation of the aforesaid law. Likewise the numerous claimed health benefits appearing on Tetley's website is in violation of the aforesaid law.

71. As FDA found in regard to the therapeutic claims made by Unilever/Lipton and Diaspora Tea & Herb Co. discussed above, the therapeutic claims on Tetley's website and on its labels establish that their products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Tetley's Misbranded Food Products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of 21 U.S.C. § 321(p). New drugs may not be legally marketed in the U.S. without ***prior*** approval from FDA as described in section 505(a) of 21 U.S.C. § 355(a). FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

72. As discussed above and as shown in Exhibits 1 and 2, the FDA has conducted reviews of similar products to Tetley's tea products and concluded that those companies were "in violation of the Federal Food, Drug, and Cosmetic Act … and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101)." FDA found the products to be misbranded stating, "Your product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use this drug safely for its intended purposes. Thus, your … product is misbranded under section 502(f)(1) of the Act in that the labeling for this drug fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)]." *See* Exhibits 1 and 2.

73. The package front panel of Tetley's Misbranded Food Products claims a level of "antioxidants" but their products do not contain any antioxidant substance or nutrient with an established RDI. Tetley makes various health related benefits to be derived from using its products but, as with the Lipton and Diaspora Tea & Herb Co. products, Tetley's tea products do not have approval from FDA to make the health related claims. Moreover, the health related claims are in violation of 21 U.S.C. § 352(f)(1) and therefore the products are misbranded.

74. Defendant has manufactured, advertised, distributed and sold products that are misbranded under California law. Misbranded products cannot be legally manufactured, advertised, distributed or sold and are legally worthless as a matter of law.

D. Defendant Has Violated California Law

75. Defendant has violated California Health & Safety Code §§ 109885 and 110390 which make it unlawful to disseminate false or misleading food advertisements that include statements on products and product packaging or labeling or any other medium used to directly or indirectly induce the purchase of a food product.

76. Defendant has violated California Health & Safety Code § 110395 which makes it unlawful to manufacture, sell, deliver, hold or offer to sell any misbranded food.

77. Defendant has violated California Health & Safety Code § 110398 which makes it unlawful to deliver or proffer for delivery any food that has been falsely advertised.

78. Defendant has violated California Health & Safety Code § 110660 because its labeling is false and misleading in one or more ways, as follows:

a. They are misbranded under California Health & Safety Code § 110665 because their labeling fails to conform to the requirements for nutrient labeling set forth in 21 U.S.C. § 343(q) and the regulations adopted thereto;

b. They are misbranded under California Health & Safety Code § 110670 because their labeling fails to conform with the requirements for nutrient content and health claims set forth in 21 U.S.C. § 343(r) and the regulations adopted thereto; and

c. They are misbranded under California Health & Safety Code § 110705 because words, statements and other information required by the Sherman Law to appear on their labeling either are missing or not sufficiently conspicuous.

79. Defendant has violated California Health & Safety Code § 110760 which makes it unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is misbranded.

80. Defendant has violated California Health & Safety Code § 110765 which makes it unlawful for any person to misbrand any food.

81. Defendant has violated California Health & Safety Code § 110770 which makes it unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for deliver any such food.

82. Defendant has violated the standard set by 21 C.F.R. § 101.2, which has been incorporated by reference in the Sherman Law, by failing to include on their product labels the nutritional information required by law.

. 83. Defendant has violated the standards set by 21 CFR §§ 101.13, and 101.54, which have been adopted by reference in the Sherman Law, by including unauthorized antioxidant claims on their products. Defendant has violated the standards set by 21 CFR §§ 101.14, and 101.65, which have been adopted by reference in the Sherman Law, by including unauthorized health and healthy claims on their products.

C. Plaintiff Purchased Defendant's Misbranded Food Products

84. Plaintiff cares about the nutritional content of food and seeks to maintain a healthy diet.

85. Plaintiff purchased Defendant's Misbranded Food Products at issue in this Complaint during the Class Period including the following products:

British Blend, Premium Black Tea


Nutrition Facts
Serving Size 1 tea bag (2.5g)
Makes 8 fl. oz. (240 mL)
Servings per Container 80
Amount Per Serving
Calories 0
% Daily Value*
Total Fat 0g 0%
Sodium 0mg 0%
Total Carb. less than 1g 0%
Protein 0g
*Percent Daily Values are based on a 2,000 calorie diet.
Ingredients: Black Tea
Tetley USA Inc. Montvale, NJ 07645
800-728-0084
DID YOU ENJOY YOUR CUP OF TETLEY?
Let us know by visiting
www.tetleyusa.com
Find out about our membership of:
www.ethicalteapartnership.org
working for a responsible tea industry.

Green Tea


Tetley
GREEN TEA
100% PURE AND NATURAL GREEN TEA
A natural source of antioxidants
40
TEA BAGS
NET WT
2.8 OZ. (79g)


That's Better, That's Tetley™
When it comes to pure, refreshing real tea taste, no other tea compares with Tetley. Tetley Green Tea is distinctively relaxing, yet powerfully restorative. To make this smooth tasting tea, Tetley only selects the finest green teas of exceptional quality. The leaves are then carefully prepared to evaporate moisture and lock in the distinct flavor. The result: a gentle, calming tea with a light golden color and fine delicate flavor.
Try our other delicious blends...
Tetley
CLASSIC BLACK TEA
CLASSIC BLACK TEA
Tetley
BRITISH BLEND
BRITISH BLEND
Tetley
GREEN TEA
DECAFFEINATED GREEN TEA
Tetley Tea: the smart choice for your healthy lifestyle
Like fruits and vegetables, tea is an excellent source of natural antioxidants which help boost the body's immune system. So, drink to your health with Tetley!
Tetley

86. Plaintiff read the labels on Defendant's Misbranded Food Products, including the antioxidant and nutrient content claims, where applicable, before purchasing them. Plaintiff would have foregone purchasing Defendant's products and bought other products readily available at a lower price.

87. Plaintiff relied on Defendant's package labeling including the antioxidant, nutrient content and health labeling claims including the "excellent source of antioxidants," "natural source of antioxidants" claims, and based and justified the decision to purchase Defendant's products in substantial part on Defendant's package labeling including the antioxidant, nutrient content and health labeling claims including the "excellent source of antioxidants," "natural source of antioxidants" claims.

88. At point of sale, Plaintiff did not know, and had no reason to know, that Defendant's products were misbranded as set forth herein, and would not have bought the products had she known the truth about them.

89 At point of sale, Plaintiff did not know, and had no reason to know, that Defendants' antioxidant, nutrient content and health labeling claims including the "excellent source of antioxidants," "natural source of antioxidants" claims were unlawful and unauthorized as set forth herein, and would not have bought the products had he known the truth about them.

90. As a result of Defendant's unlawful labeling claims including the antioxidant, nutrient content and health labeling claims including the "excellent source of antioxidants," "natural source of antioxidants" claims, Plaintiff and thousands of others in California purchased the products at issue.

91. Defendant's labeling, advertising and marketing as alleged herein is false and misleading and designed to increase sales of the products at issue. Defendant's misrepresentations are part of an extensive labeling, advertising and marketing campaign, and a reasonable person would attach importance to Defendant's representations in determining whether to purchase the products at issue.

92. A reasonable person would also attach importance to whether Defendants' products were legally salable, and capable of legal possession, and to Defendants' representations about these issues in determining whether to purchase the products at issue. Plaintiff would not have purchased Defendants' Misbranded Food Products had he known they were not capable of being legally sold or held.

CLASS ACTION ALLEGATIONS

93. Plaintiff brings this action as a class action pursuant to Federal Rule of Procedure 23(b)(2) and 23(b)(3) on behalf of the following class:

> All persons in California who purchased Defendant's (1) Classic Blend Black Tea, (2) British Blend Black Tea, (3) Pure Green Tea, (4) Iced Tea Blend Tea, and/or (5) Iced Tea Mix Tea within the last four years (the "Class").

94. The following persons are expressly excluded from the Class: (1) Defendant and its subsidiaries and affiliates; (2) all persons who make a timely election to be excluded from the

proposed Class; (3) governmental entities; and (4) the Court to which this case is assigned and its staff.

95. This action can be maintained as a class action because there is a well-defined community of interest in the litigation and the proposed Class is easily ascertainable.

96. Numerosity: Based upon Defendant's publicly available sales data with respect to the misbranded products at issue, it is estimated that the Class numbers in the thousands, and that joinder of all Class members is impracticable.

97. Common Questions Predominate: This action involves common questions of law and fact applicable to each Class member that predominate over questions that affect only individual Class members. Thus, proof of a common set of facts will establish the right of each Class member to recover. Questions of law and fact common to each Class member include, for example:

a. Whether Defendant engaged in unlawful and misleading business practices by failing to properly package and label their Misbranded Food Products sold to consumers;

b. Whether the food products at issue were misbranded or unlawfully packaged and labeled as a matter of law;

c. Whether Defendant made unlawful and misleading antioxidant claims with respect to their food products sold to consumers;

d. Whether Defendant made unlawful and misleading nutrient content and health claims with respect to their food products sold to consumers;

e. Whether Defendant violated California Bus. & Prof. Code § 17200, California Bus. & Prof. Code § 17500, and the Sherman Law;

f. Whether Plaintiff and the Class are entitled to equitable and/or injunctive relief;

g. Whether Defendant's unlawful, unfair and/or deceptive practices harmed Plaintiff and the Class; and

h. Whether Defendant was unjustly enriched by their deceptive practices.

98. Typicality: Plaintiff's claims are typical of the claims of the Class because Plaintiff bought Defendant's Misbranded Food Products during the Class Period. Defendant's unlawful, unfair and/or fraudulent actions concern the same business practices described herein irrespective of where they occurred or were received. Plaintiff and the Class sustained similar

injuries arising out of Defendant's conduct in violation of California law. The injuries of each member of the Class were caused directly by Defendant's wrongful conduct. In addition, the factual underpinning of Defendant's misconduct is common to all Class members and represents a common thread of misconduct resulting in injury to all members of the Class. Plaintiff's claims arise from the same practices and course of conduct that give rise to the claims of the Class members and are based on the same legal theories.

99. Adequacy: Plaintiff will fairly and adequately protect the interests of the Class. Neither Plaintiff nor Plaintiff's counsel have any interests that conflict with or are antagonistic to the interests of the Class members. Plaintiff has retained highly competent and experienced class action attorneys to represent their interests and those of the members of the Class. Plaintiff and Plaintiff's counsel have the necessary financial resources to adequately and vigorously litigate this class action, and Plaintiff and counsel are aware of their fiduciary responsibilities to the Class members and will diligently discharge those duties by vigorously seeking the maximum possible recovery for the Class.

100. Superiority: There is no plain, speedy or adequate remedy other than by maintenance of this class action. The prosecution of individual remedies by members of the Class will tend to establish inconsistent standards of conduct for Defendant and result in the impairment of Class members' rights and the disposition of their interests through actions to which they were not parties. Class action treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently and without the unnecessary duplication of effort and expense that numerous individual actions would engender. Further, as the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation would make it difficult or impossible for individual members of the Class to redress the wrongs done to them, while an important public interest will be served by addressing the matter as a class action. Class treatment of common questions of law and fact would also be superior to multiple individual actions or piecemeal litigation in that class treatment will conserve the resources of the Court and the litigants, and will promote consistency and efficiency of adjudication.

101. The prerequisites to maintaining a class action for injunctive or equitable relief pursuant to Fed. R. Civ. P. 23(b)(2) are met as Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive or equitable relief with respect to the Class as a whole.

102. The prerequisites to maintaining a class action pursuant to Fed. R. Civ. P. 23(b)(3) are met as questions of law or fact common to class members predominate over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

103. Plaintiff and Plaintiff's counsel are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
Business and Professions Code § 17200, *et seq.*
Unlawful Business Acts and Practices

104. Plaintiff incorporates by reference each allegation set forth above.

105. Defendant's conduct constitutes unlawful business acts and practices.

106. Defendant sold Misbranded Food Products in California during the Class Period.

107. Defendant is a corporation and, therefore, each is a "person" within the meaning of the Sherman Law.

108. Defendant's business practices are unlawful under § 17200, *et seq*. by virtue of Defendant's violations of Article 6 (misbranded food) of the Sherman Law.

109. Defendant's business practices are unlawful under § 17200, *et seq*. by virtue of Defendant's violations of § 17500, *et seq.*, which forbids untrue and misleading advertising.

110. Defendant sold Plaintiff and the Class Misbranded Food Products that were not capable of being sold legally and which were legally worthless. Plaintiff and the Class paid a premium price for the Misbranded Food Products.

111. As a result of Defendant's illegal business practices, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and to restore to any Class Member any money paid for the Misbranded Food Products.

112. Defendant's unlawful business acts present a threat and reasonable continued likelihood of deception to Plaintiff and the Class.

113. As a result of Defendant's conduct, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

SECOND CAUSE OF ACTION
Business and Professions Code § 17200, *et seq.*
Unfair Business Acts and Practices

114. Plaintiff incorporates by reference each allegation set forth above.

115. Defendant's conduct as set forth herein constitutes unfair business acts and practices.

116. Defendant sold Misbranded Food Products in California during the Class Period.

117. Plaintiff and members of the Class suffered a substantial injury by virtue of buying Defendant's Misbranded Food Products that they would not have purchased absent Defendant's illegal conduct as set forth herein.

118. Defendant's deceptive marketing, advertising, packaging and labeling of its Misbranded Food Products was of no benefit to consumers, and the harm to consumers and competition is substantial.

119. Defendant sold Plaintiff and the Class Misbranded Food Products that were not capable of being legally sold and that were legally worthless. Plaintiff and the Class paid a premium price for the Misbranded Food Products.

120. Plaintiff and the Class who purchased Defendant's Misbranded Food Products had no way of reasonably knowing that the products were not properly marketed, advertised, packaged and labeled, and thus could not have reasonably avoided the injury each of them suffered.

121. The consequences of Defendant's conduct as set forth herein outweighs any justification, motive or reason therefor. Defendant's conduct is and continues to be illegal and contrary to public policy, and is substantially injurious to Plaintiff and the Class.

122. As a result of Defendant's conduct, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

THIRD CAUSE OF ACTION
Business and Professions Code § 17200, *et seq.*
Fraudulent Business Acts and Practices

123. Plaintiff incorporates by reference each allegation set forth above.

124. Defendant's conduct as set forth herein constitutes fraudulent business practices under California Business and Professions Code sections § 17200, *et seq.* Defendant sold Misbranded Food Products in California during the Class Period.

125. Defendant's misleading marketing, advertising, packaging and labeling of the Misbranded Food Products was likely to deceive reasonable consumers, and in fact, Plaintiff and members of the Class were deceived. Defendant has engaged in fraudulent business acts and practices.

126. Defendant's fraud and deception caused Plaintiff and the Class to purchase Defendant's Misbranded Food Products that they would otherwise not have purchased had they known the true nature of those products.

127. Defendant sold Plaintiff and the Class Misbranded Food Products that were not capable of being sold legally and that were legally worthless. Plaintiff and the Class paid a premium price for the Misbranded Food Products.

128. As a result of Defendant's conduct as set forth herein, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

FOURTH CAUSE OF ACTION
Business and Professions Code § 17500, *et seq.*
Misleading and Deceptive Advertising

129. Plaintiff incorporates by reference each allegation set forth above.

130. Plaintiff asserts this cause of action for violations of California Business and Professions Code § 17500, *et seq*. for misleading and deceptive advertising against Defendant.

131. Defendant sold Misbranded Food Products in California during the Class Period.

132. Defendant engaged in a scheme of offering Misbranded Food Products for sale to Plaintiff and members of the Class by way of, *inter alia*, product packaging and labeling, and other promotional materials. These materials misrepresented and/or omitted the true contents and nature of Defendant's Misbranded Food Products. Defendant's advertisements and inducements were made within California and come within the definition of advertising as contained in Business and Professions Code §17500, *et seq.* in that such product packaging and labeling, and promotional materials were intended as inducements to purchase Defendant's Misbranded Food Products and are statements disseminated by Defendant to Plaintiff and the Class that were intended to reach members of the Class. Defendant knew that these statements were misleading and deceptive as set forth herein.

133. In furtherance of their plan and scheme, Defendant prepared and distributed within California and nationwide via product packaging and labeling, and other promotional

materials, statements that misleadingly and deceptively represented the ingredients contained in and the nature of Defendant's Misbranded Food Products. Plaintiff and the Class necessarily and reasonably relied on Defendants' materials, and were the intended targets of such representations.

134. Defendant's conduct in disseminating misleading and deceptive statements in California and nationwide to Plaintiff and the Class was and is likely to deceive reasonable consumers by obfuscating the true ingredients and nature of Defendant's Misbranded Food Products in violation of the "misleading prong" of California Business and Professions Code § 17500, *et seq*.

135. As a result of Defendant's violations of the "misleading prong" of California Business and Professions Code § 17500, *et seq.*, Defendant has been unjustly enriched at the expense of Plaintiff and the Class. Misbranded products cannot be legally sold and are legally worthless. Plaintiff and the Class paid a premium price for the Misbranded Food Products.

136. Plaintiff and the Class, pursuant to Business and Professions Code § 17535, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

FIFTH CAUSE OF ACTION
Business and Professions Code § 17500, *et seq.*
Untrue Advertising

137. Plaintiff incorporates by reference each allegation set forth above.

138. Plaintiff asserts this cause of action against Defendant for violations of California Business and Professions Code § 17500, *et seq.*, regarding untrue advertising.

139. Defendant sold Misbranded Food Products in California during the Class Period.

140. Defendant engaged in a scheme of offering Misbranded Food Products for sale to Plaintiff and the Class by way of product packaging and labeling, and other promotional materials. These materials misrepresented and/or omitted the true contents and nature of

Defendant's Misbranded Food Products. Defendant's advertisements and inducements were made in California and come within the definition of advertising as contained in Business and Professions Code §17500, *et seq*. in that the product packaging and labeling, and promotional materials were intended as inducements to purchase Defendant's Misbranded Food Products, and are statements disseminated by Defendant to Plaintiff and the Class. Defendant knew that these statements were untrue.

141. In furtherance of their plan and scheme, Defendant prepared and distributed in California and nationwide via product packaging and labeling, and other promotional materials, statements that falsely advertise the ingredients contained in Defendant's Misbranded Food Products, and falsely misrepresented the nature of those products. Plaintiff and the Class were the intended targets of such representations and would reasonably be deceived by Defendant's materials.

142. Defendant's conduct in disseminating untrue advertising throughout California and nationwide deceived Plaintiff and members of the Class by obfuscating the contents, nature and quality of Defendant's Misbranded Food Products in violation of the "untrue prong" of California Business and Professions Code § 17500.

143. As a result of Defendant's violations of the "untrue prong" of California Business and Professions Code § 17500, *et seq.*, Defendant has been unjustly enriched at the expense of Plaintiff and the Class. Misbranded products cannot be legally sold and are legally worthless. Plaintiff and the Class paid a premium price for the Misbranded Food Products.

144. Plaintiff and the Class, pursuant to Business and Professions Code § 17535, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

SIXTH CAUSE OF ACTION
Consumers Legal Remedies Act, Cal. Civ. Code §1750, *et seq.*

145. Plaintiff incorporates by reference each allegation set forth above.

146. This cause of action is brought pursuant to the CLRA. This cause of action does not currently seek monetary relief and is limited solely to injunctive relief. Plaintiff intends to amend this Complaint to seek monetary relief in accordance with the CLRA after providing Defendant with notice pursuant to Cal. Civ. Code § 1782.

147. At the time of any amendment seeking damages under the CLRA, Plaintiff will demonstrate that the violations of the CLRA by Defendant were willful, oppressive and fraudulent, thus supporting an award of punitive damages.

148. Consequently, Plaintiff and the Class will be entitled to actual and punitive damages against Defendant for its violations of the CLRA. In addition, pursuant to Cal. Civ. Code § 1782(a)(2), Plaintiff and the Class will be entitled to an order enjoining the above-described acts and practices, providing restitution to Plaintiff and the Class, ordering payment of costs and attorneys' fees, and any other relief deemed appropriate and proper by the Court pursuant to Cal. Civ. Code § 1780.

149. Defendant's actions, representations and conduct have violated, and continue to violate the CLRA, because they extend to transactions that are intended to result, or which have resulted, in the sale of goods or services to consumers.

150. Defendant sold Misbranded Food Products in California during the Class Period.

151. Plaintiff and members of the Class are "consumers" as that term is defined by the CLRA in Cal. Civ. Code §1761(d).

152. Defendant's Misbranded Food Products were and are "goods" within the meaning of Cal. Civ. Code §1761(a).

153. By engaging in the conduct set forth herein, Defendant violated and continues to violate Sections 1770(a)(5), (7) (9), and (16) of the CLRA, because Defendant's conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices in that they misrepresent the particular ingredients, characteristics, uses, benefits and quantities of the goods.

154. By engaging in the conduct set forth herein, Defendant violated and continues to violate Section 1770(a)(7) of the CLRA, because Defendant's conduct constitutes unfair

methods of competition and unfair or fraudulent acts or practices in that they misrepresent the particular standard, quality or grade of the goods.

155. By engaging in the conduct set forth herein, Defendant violated and continues to violate Section 1770(a)(9) of the CLRA, because Defendant's conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices in that they advertise goods with the intent not to sell the goods as advertised.

156. By engaging in the conduct set forth herein, Defendant has violated and continues to violate Section 1770(a)(16) of the CLRA, because Defendant's conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices in that they represent that a subject of a transaction has been supplied in accordance with a previous representation when they have not.

157. Plaintiff requests that the Court enjoin Defendant from continuing to employ the unlawful methods, acts and practices alleged herein pursuant to Cal. Civ. Code § 1780(a)(2). If Defendant is not restrained from engaging in these practices in the future, Plaintiff and the Class will continue to suffer harm.

SEVENTH CAUSE OF ACTION
Restitution Based on Unjust Enrichment/Quasi-Contract

158. Plaintiff incorporates by reference each allegation set forth above. As a result of Defendant's unlawful, fraudulent and misleading labeling, advertising, marketing and sales of Defendant's Misbranded Food Products, Defendant was enriched at the expense of Plaintiff and the Class.

159. Defendant sold Misbranded Food Products to Plaintiff and the Class that were not capable of being sold or held legally and which were legally worthless. It would be against equity and good conscience to permit Defendant to retain the ill-gotten benefits they received from Plaintiff and the Class, in light of the fact that the products were not what Defendant purported them to be. Thus, it would be unjust and inequitable for Defendant to retain the benefit without restitution to Plaintiff and the Class of all monies paid to Defendant for the products at issue.

160. As a direct and proximate result of Defendant's actions, Plaintiff and the Class have suffered damages in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION
Beverly-Song Act (Cal. Civ. Code § 1790, *et seq.*)

161. Plaintiff incorporates by reference each allegation set forth above.

162. Plaintiff and members of the Class are "buyers" as defined by Cal. Civ. Code § 1791(b).

163. Defendant is a "manufacturer" and "seller" as defined by Cal. Civ. Code § 1791(j) & (l).

164. Defendant's food products are "consumables" as defined by Cal. Civ. Code § 1791(d).

165. Defendant's nutrient and health content claims constitute "express warranties" as defined by Cal. Civ. Code § 1791.2.

166. Defendant, through its package labels, creates express warranties by making the affirmation of fact and promising that their Misbranded Food Products comply with food labeling regulations under federal and California law.

167. Despite Defendant's express warranties regarding their food products, it does not comply with food labeling regulations under federal and California law.

168. Defendant breached its express warranties regarding its Misbranded Food Products in violation of Cal. Civ. Code § 1790, *et seq.*

169. Defendant sold Plaintiff and members of the Class Misbranded Food Products that were not capable of being sold or held legally and which were legally worthless. Plaintiff and the Class paid a premium price for the Misbranded Food Products.

170. As a direct and proximate result of Defendant's actions, Plaintiff and the Class have suffered damages in an amount to be proven at trial pursuant to Cal. Civ. Code § 1794.

171. Defendant's breaches of warranty were willful, warranting the recovery of civil penalties pursuant to Cal. Civ. Code § 1794.

NINTH CAUSE OF ACTION
Magnuson-Moss Act (15 U.S.C. § 2301, *et seq.*)

172. Plaintiff incorporates by reference each allegation set forth above.

173. Plaintiff and members of the Class are "consumers" as defined by 15 U.S.C. § 2301(3).

174. Defendant is a "supplier" and "warrantor" as defined by 15 U.S.C. § 2301(4) & (5).

175. Defendant's food products are "consumer products" as defined by 15 U.S.C. § 2301(1).

176. Defendant's nutrient and health content claims constitute "express warranties."

177. Defendant, through its package labels, creates express warranties by making the affirmation of fact and promising that its Misbranded Food Products comply with food labeling regulations under federal and California law.

178. Despite Defendant's express warranties regarding their food products, it does not comply with food labeling regulations under federal and California law.

179. Defendant breached its express warranties regarding their Misbranded Food Products in violation of 15 U.S.C. §§ 2301, *et seq.*

180. Defendant sold Plaintiff and members of the Class Misbranded Food Products that were not capable of being sold or held legally and which were legally worthless. Plaintiff and the Class paid a premium price for the Misbranded Food Products.

181. As a direct and proximate result of Defendant's actions, Plaintiff and the Class have suffered damages in an amount to be proven at trial.

JURY DEMAND

Plaintiff hereby demands a trial by jury of her claims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, and on behalf of the general public, prays for judgment against Defendant as follows:

A. For an order certifying this case as a class action and appointing Plaintiff and his

counsel to represent the Class;

B. For an order awarding, as appropriate, damages, restitution or disgorgement to Plaintiff and the Class for all causes of action other than the CLRA, as Plaintiff does not seek monetary relief under the CLRA, but intends to amend his Complaint to seek such relief;

C. For an order requiring Defendant to immediately cease and desist from selling their Misbranded Food Products in violation of law; enjoining Defendant from continuing to market, advertise, distribute, and sell these products in the unlawful manner described herein; and ordering Defendants to engage in corrective action;

D. For all equitable remedies available pursuant to Cal. Civ. Code § 1780;

E. For an order awarding attorneys' fees and costs;

F. For an order awarding punitive damages;

G. For an order awarding pre-and post-judgment interest; and

H. For an order providing such further relief as this Court deems proper.

Dated: May 11, 2012

Respectfully submitted,

Ben F. Pierce Gore

Ben F. Pierce Gore (SBN 128515)
PRATT & ASSOCIATES
1901 S. Bascom Avenue, Suite 350
Campbell, CA 95008
Telephone: (408) 429-6506
Fax: (408) 369-0752
pgore@prattattorneys.com

Exhibit 1

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Unilever United States, Inc. 8/23/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

August 23,2010

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Michael B. Polk
President of Unilever Americas
Unilever, Inc.
700 Sylvan Avenue
Englewood, NJ 07632-3113

Re: CFSAN-OC-10-24

Dear Mr. Polk:

The Food and Drug Administration (FDA) has reviewed the label for your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product and reviewed your labeling for this product on your websites, www.lipton.com [1] and www.liptont.com [2] in August 2010. Based on our review, we have concluded that this product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at www.fda.gov [3].

A link to .your website, www.lipton.com [4]. appears on your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product label. This website directs U.S. visitors to another website, www.liptont.com [5]. We have determined that your websites, www.lipton.com [6] and www.liptont.com [7]. are labeling within the meaning of section 201(m) of the Act for your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product.

Unapproved New Drug

Your website, www.liptont.com [8]. also promotes your Lipton Green Tea 100% Natural Naturally Decaffeinated product for conditions that cause it to be a drug under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)].

For example, your webpage entitled "Tea and Health," subtitled "Heart Health Research" and further subtitled "Cholesterol Research" bears the following claim: "[F]our recent studies in people at risk for coronary disease have shown a significant cholesterol lowering effect from tea or tea flavonoids ... One of these studies, on post-menopausal women, found that total cholesterol was lowered by 8% after drinking 8 cups of green tea daily for 12 weeks ...."

The therapeutic claims on your website establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. Your Lipton Green Tea 100% Natural Naturally Decaffeinated product is not generally recognized as safe and effective for the above referenced uses and, therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Your Lipton Green Tea 100% Natural Naturally Decaffeinated product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use this drug safely for its intended purposes. Thus, your Lipton Green Tea 100% Natural Naturally Decaffeinated product is misbranded under section 502(f)(1) of the Act in that the labeling for this drug fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)] .

Unauthorized Nutrient Content Claims

Under section 403(r)(1)(A) of the Act [21 U.S.C. 343(r)(1)(A)], a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term

"antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.

Your webpage entitled "Tea and Health" and subtitled "Tea Antioxidants" includes the statement, "LIPTON Tea is made from tea leaves rich in naturally protective antioxidants." The term "rich in" is defined in 21 CFR 101.54(b) and may be used to characterize the level of antioxidant nutrients (21 CFR 101.54(g)(3)). However, this claim does not comply with 21 CFR 101.54(g)(4) because it does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients. Thus, this claim misbrands your product under section 403(r)(2)(A)(i) of the Act.

This webpage also states that "tea is a naturally rich source of antioxidants." The term "rich source" characterizes the level of antioxidant nutrients in the product and, therefore, this claim is a nutrient content claim (see section 403(r)(1) of the Act and 21 CFR 101.13(b)). Even if we determined that the term "rich source" could be considered a synonym for a term defined by regulation (e.g., "high" or "good source"), nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). The claim "tea is a naturally rich source of antioxidants" does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients, as required by 21 CFR 101.54(g)(4). Thus, this claim misbrands your product under section 403(r)(2)(A)(i) of the Act.

The product label back panel includes the statement "packed with protective FLAVONOID ANTIOXIDANTS." The term "packed with" characterizes the level of flavonoid antioxidants in the product; therefore, this claim is a nutrient content claim (see section 403(r)(1) of the Act and 21 CFR 101.13(b)). Even if we determined that the term "packed with" could be considered a synonym for a term defined by regulation, nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). The claim "packed with FLAVONOID ANTIOXIDANTS" does not comply with 21 CFR 101.54(g)1) because no RDI has been established for flavonoids. Thus, this unauthorized nutrient content claim causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

We note that your label contains a chart entitled "Flavonoid Content of selected beverages and foods." The chart appears to compare the amounts of antioxidants in your product with the amount of antioxidants in orange juice, broccoli, cranberry juice and coffee. However, the information provided may be misinterpreted by the consumer because although the chart is labeled, in part, "Flavonoid Content," the y-axis is labeled "AOX"; therefore, the consumer might believe that the chart is stating the total amount of antioxidants rather than specifically measuring the amount of flavonoids in the product.

You should take prompt action to correct these violations. Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Latasha A. Robinson, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

/s/

Jennifer A. Thomas
Acting Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: FDA New Jersey District

Close Out Letter

- Unilever United States, Inc. - Close Out Letter 5/10/11 [9]

Links on this page:

1. http://www.lipton.com/
2. http://www.liptont.com/
3. http://www.fda.gov
4. http://www.lipton.com/
5. http://www.liptont.com/
6. http://www.lipton.com/
7. http://www.liptont.com/
8. http://www.liptont.com/
9. /ICECI/EnforcementActions/WarningLetters/2010/ucm267398.htm

Exhibit 2

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Diaspora Tea & Herb dba Rishi Tea 4/20/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Minneapolis District Office
Central Region
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

April 20, 2011

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 11 – 21

Joshua Kaiser
President and Co-owner
Diaspora Tea & Herb Co., LLC
427 East Stewart Street
Milwaukee, Wisconsin 53207

Dear Mr. Kaiser:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address http://www.rishi-tea.com/store/index.php [1] in January 2011. FDA has determined that your Oolong Tea, Ginger, Organic Botanical, Green Oolong Tea, 100% Premium Tealeaf Powder, and Pu-erh Tea products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1)(B). The therapeutic claims on your website establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Additionally, FDA has determined that your Yerba Maté Shade Grown, Organic Yerba Maté, White Tea, Pu-erh Tea, Green Oolong Tea, 100% Premium Tealeaf Powder, Matcha, 100% Premium Tea Powder, Blueberry Rooibos, Organic Fair Trade Rooibos Blend, Green Rooibos (Green Bush), Organic Fair Trade Botanical, and Super Green, Organic Japanese Green Tea products are also misbranded within the meaning of section 403(r)(1)(A) of the Act, 21 U.S.C. § 343(r)(1)(A). The marketing of these products with these claims violates the Act. You can find copies of the Act through links on FDA's home page at http://www.fda.gov [2].

I. Unapproved New Drugs

Examples of disease claims on your website http://www.rishi-tea.com/store/ [3] index.php include:

Ginger, Organic Botanical

- "[G]inger is used in food and drinks as a preventive medicine against colds [and] flus."

Green Oolong Tea, 100% Premium Tealeaf Powder

- "The powerful antioxidants found in tea are believed to help prevent cancer [and] lower cholesterol...."

Pu-erh Tea

- "Recent research suggests that consuming 5-8 cups of Pu-erh Tea each day can reduce cholesterol and plaque of the arteries."

Oolong Tea

- "Regular consumption of Oolong Tea is linked to the reduction of plaque in the arteries, reduction of cholesterol and lowering of blood sugar."
- "Oolong Tea is...prized for its cholesterol reducing...."

Your Oolong Tea, Ginger, Organic Botanical, Green Oolong Tea, 100% Premium Tealeaf Powder and Pu-erh Tea products are not generally recognized as safe and effective for the above referenced uses and, therefore, are also "new drugs" under section 201(p) of the Act, 21 U.S.C. § 321(p). New drugs may not be legally marketed in the U.S. without prior approval from FDA, as described in section 505(a) of the Act, 21 U.S.C. § 355(a). FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

II. Unauthorized Nutrient Content Claims

Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the

food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. Characterizing the level of a nutrient in food labeling of a product without complying with specific requirements pertaining to nutrient content claims for that nutrient misbrands the product under section 403(r)(1)(A) of the Act.

Nutrient content claims that use the defined terms "rich in" or "high" may be used in the labeling of a food only if the food contains 20 percent or more of the daily value (DV) of that nutrient per reference amount customarily consumed (RACC), Title 21, Code of Federal Regulations (21 CFR), 101.54(b)(1). Such claims may not be made about a nutrient for which there is no established DV. However, your website bears "high" and "rich in" nutrient content claims about nutrients for which there are no established DV.

The following are examples of unauthorized "high" and "rich in" nutrient content claims on your website:

Pu-erh Tea

- "[R]ich in Tea Polyphenols and Theaflavins...rich in Thearubigin and Theabrownin...."

Super Green, Organic Japanese Green Tea

- "Super Green is...high in amino acids...."

White Tea

- "White Tea...contain[s] high concentrations of...L-Theanine Amino Acid."

Additionally, your website bears nutrient content claims using the term "antioxidant." Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a Recommended Daily Intake (RDI) must have been established for each of the nutrients that are the subject of the claim, 21 CFR 101.54(g)(1), and these nutrients must have recognized antioxidant activity, 21 CFR 101.54(g)(2). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e), 21 CFR 101.54(g)(3). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity, 21 CFR 101.54(g)(4). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.

The following are examples of nutrient content claims on your website that use the term "antioxidant" but do not include the names of the nutrients that are the subject of the claim as required under 21 CFR 101.54(g)(4):

Yerba Maté Shade Grown, Organic Yerba Maté

- "Yerba Maté is...rich in... antioxidants."

Blueberry Rooibos, Organic Fair Trade Rooibos Blend

- "Antioxidant-rich...."

Green Rooibos (Green Bush), Organic Fair Trade Botanical

- "Caffeine-free Green Rooibos...contain[s] high concentrations of antioxidants...."

Additionally, the following are examples of nutrient content claims on your website that use the term "antioxidant," but where the nutrients that are the subject of the claim do not have an established RDI as required under 21 CFR 101.54(g)(1):

White Tea

- "White Tea... contain[s] high concentrations of... antioxidant polyphenols (tea catechins)...."

Matcha, 100% Premium Tea Powder

- "Antioxidant rich...222mg polyphenols per serving!"

Genmai Green Tea, 100% Premium Tealeaf Powder

- "Antioxidant rich...65mg polyphenols per serving!"

Green Oolong Tea, 100% Premium Tealeaf Powder

- "Antioxidant rich...109mg polyphenols per serving!"
- "[R]ichest sources of flavonoid antioxidants...."

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your website, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products, 21 U.S.C. §§ 332 and 334. You should take prompt action to correct these violations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these violations and to prevent similar violations. You should include in your response documentation such as revised labels or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

Your reply should be sent to the attention of Compliance Officer Tyra S. Wisecup at the address on the letterhead.

Sincerely,

/s/

Gerald J. Berg
Director
Minneapolis District

Close Out Letter

- Diaspora Tea & Herb Co., LLC - Close Out Letter 2/3/12[4]

Links on this page:

Exhibit 3

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Redco Foods, Inc. 2/22/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

FEB 22 2010

WARNING LETTER

VIA OVERNIGHT MAIL

Mr. Douglas N. Farrell, General Manager
Redco Foods, Inc.
One Hansen Island
Little Falls, NY 13365

Re: CFSAN-OC-10-10

Dear Mr. Farrell:

The Food and Drug Administration (FDA) has reviewed the label for your "Salada Naturally Decaffeinated Green Tea" product and your website www.greentea.com. Based on our review, we have concluded that your green tea products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at www.fda.gov.

Unapproved New Drug

Your website, www.greentea.com. promotes your green tea products for conditions that cause them to be drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. Examples of disease claims that cause your products to be drugs include:

On a web page entitled "About Green Tea":

"A Steaming Cup of Medicine" Article:

- "And today, scientific [sic] are ... finding that green tea can ... inhibit the cancer process at virtually every stage, regulate cholesterol levels ... and ward off viruses, fungi and food-borne bacteria."
- "[I]t also helps inhibit dental plaque formation, lower the risk of type 2 diabetes ...."

"The Origins of Tea" Article:

- "By this time, tea was prized as a medicine that could cure digestive disorders ...
- "The tea leaves were also applied externally as a paste to ease the pains of rheumatism."

"Is Green Tea a Brain Food?" Article:

- "[R]ecent studies of the effects of green tea's catechins on animal brains are intriguing:

o "* Less buildup of plaque[.] Finally, mice specially bred to develop Alzheimer's disease developed up to 54% less beta-amyloid buildup in their brains when they were given daily injections of the green tea catechin EGCg.... Beta-amyloid plaques are believed to be a major cause of the brain cell death and dissue [tissue] loss seen in Alzheimer's disease."

The therapeutic claims on your website establish that your green tea products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Your green tea products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201 (p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Your green tea products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, your green tea products are misbranded under section 502(f)(1) of the Act in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

Unauthorized Health Claims

Your green tea products are further misbranded under section 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)] because its labeling bears unauthorized health claims. Your website, www.greentea.com. was reviewed and was found to contain a number of unauthorized health claims, including:

"Green Tea and the FDA: Who's Right?" Article:

- "[O]ver the past 25 years, countless studies showing the positive effect of green tea on several important risk factors for cardiovascular disease have been published in scientific journals."

- "[M]ost studies have shown that green tea reduces certain CVD risk factors with a daily intake of 4-5 cups ...."

The above claims are unauthorized health claims because there is no health claim authorized by regulation or the Act that provides for health claims that characterize the relationship between green tea and cardiovascular disease.

Unauthorized Nutrient Content Claims

Under section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)], a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b)). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)].

The principal display panel of the product label includes the statement "Fortified with Purple Antioxidants [/] Fortified with Grapeskins, Rooibos (Red Tea), Anthocyanins ..." In the context of the label, the term "antioxidants" refers, in part, to grapeskins, rooibos (red tea), and anthocyanins. The term "fortified" is defined by regulation and may be used to describe the level of certain substances for which an RDI or Daily Reference Value (DRV) has been established [21 CFR 101.54(e)]. However, there are no RDIs or DRVs for grapeskins, rooibos (red tea) or anthocyanins. Therefore, the claim "Fortified with Grapeskins, Rooibos (Red Tea), Anthocyanins" is unauthorized and misbrands your product under section 403(r)(1)(A) of the Act.

In addition, nutrient content claims using the term "antioxidant" may only be made for nutrients for which a Reference Daily Intake (RDI) has been established [21 CFR 101.54(g)(1)]. As noted above, there are no RDIs for grapeskins, rooibos (red tea) or anthocyanins. Therefore, the claim "Fortified with Purple Antioxidants ... Grapeskins. Rooibos (Red Tea), Anthocyanins" is an unauthorized nutrient content claim that causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The label for this product also bears the unauthorized nutrient content claim "One of the antioxidants known as EGCG (Epigallocatechin gallate) is abundantly found in green tea leaves." This claim is a nutrient content claim because "abundantly found" characterizes the level of EGCG in your product [see section 403(r)(1) of the Act (21 U.S.C. § 343(r)(1)) and 21 CFR 101.13(b)]. Even if we determined that the term "abundantly found" could be considered a synonym for a term defined by regulation (e.g., "high" or "good source"), nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). This claim does not comply with 21 CFR 101.54(g)(1) because no RDI has been established for EGCG. Thus, this unauthorized nutrient content claim causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

You should take prompt action to correct these violations. Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Kathleen M. Lewis, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint

Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

/S/

Roberta F. Wagner
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: FDA New York District

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 U.S Department of **Health & Human Services**

Links on this page:

Exhibit 4

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Fleminger Inc

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

FEB 22 2010

WARNING LETTER

VIA OVERNIGHT MAIL

Dr. Lee
Dba Dr. Lee's TeaForHealth™
Fleminger Inc.
160 Hawley Lane, Suite 205
Trwnbull, CT 06611

CFSAN-OC-10-01

Dear Dr. Lee:

This is to advise you that the Food and Drug Administration (FDA) reviewed your websites on December 8, 2009 at the Internet addresses www.teaforhealth.com and www.greenteahaus.com. The FDA has determined that your TeaForHealth™ green tea products, Dr. Lee's TeaForHealth® 710EGCG™ inabottle™ Green Tea and Tea For Health® 710EGCG™ Ready-To-Drink Natural Brewed Green Tea, are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Act [21 U.S.C. § 321(g)(I)], new drugs under section 201(P) of the Act [21 USC § 321(P)], and misbranded under sections 403(a)(1), 403(r)(1)(A), 403(r)(1)(B), and 502(f)(1) of the Federal Food, Drug; and Cosmetic Act (the Act) [21 U.S.C. §§ 343(a)(I), 343(r)(1)(A), 343(r)(1)(B), and 352(f)(1)]. The marketing of the products with these claims violates the Act.

I. Unapproved New Drugs:

Your website, www.teaforhealth.com. redirects the consumer to another site of yours, www.greenteahaus.com. that makes several claims and provides links to articles, brochures, and other "educational materials." Examples of the disease claims observed on www.greenteahaus.com include:

- "Produced according to NCI specifications*" and "Green tea of the NCI-defined strength*" where the asterisks lead the consumer to the text: "Based on the pharmacodynamics data published by the National Cancer Institute (NCI)...daily consumption of 1,200 ml (40 ounces) of green tea containing 710 mcg/ml (-)epigallocatechin gallate (EGCG).. .is equivalent to 1.5 times the lowest anticancer effective dose in a 70-kg (154-lb.) person. Up to 10 times the lowest effective dose can be well tolerated by cancer patients if properly administered."
- "[G]reen tea may be also useful in enhancing the anticancer effects of conventional chemotherapeutics (chemo), even synergistically with the less toxic antineoplastic drugs of the quinolone family, and in controlling Alzheimer's disease, Parkinson's disease, obesity, blood thrombosis, cardiovascular diseases, diabetes ... viral infections, liver damage ... and antibiotic-resistant bacterial infections."
- "As a COX-2 inhibitor, green tea may provide some of the benefits that Vioxx and Celebrex had offered to patients without their toxicities."

Examples of disease claims on www.greenteahaus.com in the form of headings of categorized "educational materials" include:

- "[A]nticancer effects of green tea and the EGCG level of the green tea used in cancer research"
- "Green tea or its components may enhance anticancer effects of drugs and prolong cancer patient survival"
- "Neuroprotection of green tea against Alzheimer's disease and Parkinson's disease"
- "Green tea is anti-thrombotic and may help blood circulation"
- "Antiviral effects of green tea"
- "Liver protection of green tea against hepatitis and other injuries"
- "Green tea enhances the antimicrobial effects of antibiotics, especially that against methicillin-resistant strains of staphylococcus aureus, MRSA"

Your website, www.greenteahaus.com. links to the full text of a brochure entitled, "The Truth in Tea." Examples of disease claims in this brochure include:

- "The anticancer activities of green tea or its components, especially the antioxidants, for example, EGCG, are widely ranged, starting at inhibition of the formation of exogenous carcinogens in the stomach to interference with tumor initiation, promotion and progression."
- "The women drinking 10 Japanese cups (1200-1500 ml) or more green tea a day enjoy an average 8.7 more cancer-free years than low volume tea drinkers do ... The result showed a reduction of breast cancer rate in association with drinking green tea and their dose-dependent relationship...."
- "Heavy green tea consumption was found to be associated with reduced recurrence of breast cancer in [Stage I and Stage II breast cancer] patients ... "
- "[G]reen tea... [was] found to enhance the anticancer effects of certain chemotherapeutic drugs, like 5- fluorouracil and doxorubicin. Thus green tea as dietary supplement may reduce the required dosage of certain anticancer drugs and minimize their adverse side effects."
- "Green tea...has been shown to be potentially beneficial in the fight against viral infections through the following mechanisms:
  - o "Antimutagenic at the molecular level - to reduce the chance of virus mutation. Viral mutation has been a big problem in treating SARS and HIV patients."
  - o "Antiviral at the cellular level (inhibit replication of viral particles, e.g., by interfering with HIV attachment to CD4 lymphocytes).
  - o "Boosting the immunity of the human body (an old concept in Chinese medicine, but quite new in western medicine) against viral and bacterial infections."
  - o "Enhancing the antimicrobial activity of the antibiotics against secondary bacterial infections reducing the chance of developing drug resistance and working synergistically with the antibacterial drugs, such as restoring the MRSA sensitivity to methicillin."

These therapeutic claims on your website establish that the products are drugs under section 201(g)(1) of the Act, because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Your products are also "new drugs" under section 201 (P) of the Act, because they are not generally recognized as safe and effective for the above referenced conditions. New drugs may not be legally marketed in the U.S. without prior approval from FDA, as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. In addition, your products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, your products are misbranded under section 502(f)(1) of the Act, in that their labeling fails to bear adequate directions for use.

II. Unauthorized Health Claims:

Examples of health claims observed on www.teaforhealth.com include:

- "Green tea may reduce the risk of breast and prostate cancers. The FDA has concluded that there is credible evidence supporting this claim although the evidence is limited."

Examples of health claims on www.greenteahaus.com in the form of headings of categorized "educational materials" include:

- "Epidemiological and clinical studies on the relationship between cancer risk and the consumption of green tea..."

Examples of health claims in "The Truth in Tea" include:

- "[H]igh consumption of green tea [is] associated with reduced cancer rates of the breast, esophagus, stomach, colon, rectum, pancreas, urinary bladder, prostate, lung, liver, and ovary... "
- "Recent medical research has provided evidence that drinking green tea may reduce the risk of fatal heart attack, stroke, Alzheimer's disease, Parkinson's disease, help reduce body fat and help fight viral infection."

These claims cause your products to be misbranded under section 403(r)(1)(B) of the Act in that they are health claims that have not been authorized by regulation or the Act. In a letter issued to you on June 30, 2005 ("the June 2005 letter"), FDA articulated two health claims for green tea for which FDA intended to consider exercising enforcement discretion:

1. "Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer."
2. "One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggest that drinking green tea may reduce this risks. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer."

The claims presented on your websites are not consistent with either of these qualified health claims.

III. Unauthorized Nutrient Content Claims:

Examples of unauthorized nutrient content claims on www.teaforhealth.com include:

- "Drink high antioxidant green tea -- for your health!"

Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of

such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands the product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b)). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g .. asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidan' activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A) of the Act.

Your claim, "Drink high antioxidant green tea," is an unauthorized nutrient content claim. The term "high" is defined in 21 CFR 101.54(b) and may be used to characterize the level of antioxidant nutrients (21 CFR 101.54(g)(3)). However, this claim does not comply with 21 CFR 101.54(g)(4) because it does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients. Thus, this claim is unauthorized and causes your product to be misbranded under section 403(r)(2)(A) of the Act.

IV. False or Misleading Labeling:

Your website, www.teaforhealth.com. makes false or misleading statements regarding FDA's conclusions on the relationship between green tea consumption and cancer risk, including:

- "Green tea may reduce the risk of breast and prostate cancers. The FDA has concluded that there is credible evidence supporting this claim although the evidence is limited."
- "Green tea happens to be one of the components in our diet whose anticancer effects have been supported by solid scientific evidence. The consumers are entitled to the whole truth....The fully disclosed accurate language of the [FDA] granted health claims should read as follows (with my clarifying notes added in parentheses):

  1. 'Two studies **(which were conducted among Japanese living in the northern rural Miyagi prefecture where no tea plantations are in existence)** do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study **(which was conducted among green tea drinking Asian women living in Los Angeles, CA, U.S.A.)** suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer **(if a green tea similar to those marketed in northern rural Japan is consumed)**.'

  2. 'One weak and limited study **(which was conducted among Japanese living in the northernmost island of Hokkaido where no tea trees can survive)** does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study **(which was conducted among the local residents of Hangzhou, the traditional green tea plantation and production capital of China)** suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer **(if a green tea similar to those marketed in Hokkaido of Japan is consumed)**.",***1***

In the June 2005 letter, FDA informed you of the results of our review of the scientific evidence and other information submitted as part of the petition filed under docket 2004Q-0083 regarding green tea and various cancers. We advised you of our conclusions that there is very limited credible evidence for qualified health claims regarding the consumption of green tea and a reduced risk of prostrate cancer and the consumption of green tea and a reduced risk of breast cancer. We also advised you of our conclusion that there is not credible evidence to support a claim with respect to all other types of cancer. The June 2005 letter articulated FDA's intent to consider exercising enforcement discretion for the two qualified health claims cited in section II above.

FDA worded the conclusions and qualified health claims in the June 2005 letter to reflect our careful evaluation and ranking of the level of scientific evidence linking green tea consumption and the risk of various cancers.***2*** Your statement, "FDA has concluded that there is credible evidence supporting this claim although the evidence is limited," mischaracterizes FDA's conclusions about the level of evidence suggesting green tea reduces the risk of breast and prostate cancers. Moreover, your edits to FDA's conclusions in the qualified health claims' language and your assertions that your edits make the qualified health claims "fully disclosed" and "accurate" suggest that your rendition of FDA's qualified health claims more accurately reflects and more fully discloses FDA's conclusions than FDA's non-embellished version. These statements alter the meaning of FDA's language and misrepresent FDA's conclusions. Thus, these statements cause your products to be misbranded under section 403(a)(1) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your websites, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 §§ U.S.C. 332 and 334]. You should take prompt action to

correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should include each step that has been or will be taken to completely correct the labeling violations and to prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that the correction has been achieved. If applicable, please include a copy of your revised label. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may respond in writing to Felicia B. Williams, Compliance Officer, Division of Enforcement, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740.

Sincerely,
/S/

Roberta Wagner
Director
Office of Compliance
Center for Food Safety and
Applied Nutrition

cc: New England District

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1 http://www.teaforhealth.comIPR/2006/082806.htm

2 For more information on this process generally, see FOOD & DRUG ADMIN., *Guidance for Industry and FDA: Interim Evidence-based Ranking System for Scientific Data* (July 2003), *available at* http://www.fda.gov/OHRMS/DOCKETS/98fr/03N-0069-gdl0001.pdf.

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